



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

0767 5 NOV -7 P1:58

SEP 22 2005

Ms. Kristin Foster  
Administrator  
New Chapter, Inc.  
22 High Street  
P.O. Box 1947  
Brattleboro, Vermont 05302

Dear Ms. Foster:

This is in response to your letters of September 6, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that New Chapter, Inc. is making the following claims, among others, for the following products:

**Probiotic Immune Support™**

“Enhances immune resistance during cold and flu season;”

**Supercritical Sinus and Respiratory**

“[P]romote comfort during the cold and flu season.”

**Headache Relief™**

“[R]elief from headaches and other painful conditions....”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products (including the product name “Headache Relief”) suggest that they are intended to treat, prevent, or mitigate diseases, namely the common cold and influenza and diseases for which pain is a characteristic sign or symptom. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

97S 0163 LET 845

Page 2 - Ms. Margaret E. Kilroy

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal line extending to the right.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

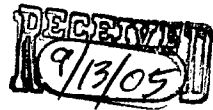
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93



This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is Probiotic Immune Support™.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Enhances immune resistance during cold and flu season

(Statement 2): 10 beneficial non-centrifuged probiotics cultured in immune-boosting fruits, vegetables, and herbs

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	American Elderberry, Spinach, Parsley, Okra, Oregano, Cumin, Ginger, Arabinogalactan, Milk, Nutritional Yeast, and Bacteria ( <i>L. casei</i> , <i>L. Plantarum</i> , <i>L. salivarius</i> , <i>L. acidophilus</i> , <i>L. rhamnosus</i> , <i>S. thermophilus</i> , <i>B. bifidum</i> , <i>B. infantis</i> , <i>B. longum</i> , <i>B. breve</i> )
2.	American Elderberry, Spinach, Parsley, Okra, Oregano, Cumin, Ginger, Arabinogalactan, Milk, Nutritional Yeast, and Bacteria ( <i>L. casei</i> , <i>L. Plantarum</i> , <i>L. salivarius</i> , <i>L. acidophilus</i> , <i>L. rhamnosus</i> , <i>S. thermophilus</i> , <i>B. bifidum</i> , <i>B. infantis</i> , <i>B. longum</i> , <i>B. breve</i> )

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	Probiotic Immune Support™	Label and Labeling
2.	Probiotic Immune Support™	Label and Labeling

I, Kristin Foster, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: Sept 6, 2005 By: Kristin Foster, QA Administrator  
[Name]  
[Title]

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Probiotic Immune Support™**.

The text of each structure-function statement for which notification is now being given is:

(Statement 3): Probiotic Immune Support

(Statement 4): Rather than centrifuging or removing the culturing media as in other products, New Chapter formulates its culturing media to deliver phytonutrient-rich herbs and foods designed for maximizing the probiotics' life supportive effects.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<b><u>Statement Number</u></b>	<b><u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u></b>
3.	American Elderberry, Spinach, Parsley, Okra, Oregano, Cumin, Ginger, Arabinogalactan, Milk, Nutritional Yeast, and Bacteria ( <i>L. casei</i> , <i>L. Plantarum</i> , <i>L. salivarius</i> , <i>L. acidophilus</i> , <i>L. rhamnosus</i> , <i>S. thermophilus</i> , <i>B. bifidum</i> , <i>B. infantis</i> , <i>B. longum</i> , <i>B. breve</i> )
4.	American Elderberry, Spinach, Parsley, Okra, Oregano, Cumin, Ginger, Arabinogalactan, Milk, Nutritional Yeast, and Bacteria ( <i>L. casei</i> , <i>L. Plantarum</i> , <i>L. salivarius</i> , <i>L. acidophilus</i> , <i>L. rhamnosus</i> , <i>S. thermophilus</i> , <i>B. bifidum</i> , <i>B. infantis</i> , <i>B. longum</i> , <i>B. breve</i> )

The following identifies the brand name of each supplement for which a statement is made:

<b><u>Statement Number</u></b>	<b><u>Brand Name</u></b>	<b><u>Label or Labeling?</u></b>
3.	Probiotic Immune Support™	Label and Labeling
4.	Probiotic Immune Support™	Label

I, Kristin Foster, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: Sept 6, 2005 By: Kristin Foster, QA Administrator  
[Name]  
[Title]

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Probiotic Immune Support™**.

The text of each structure-function statement for which notification is now being given is:

(Statement 5): *Probiotics with a Purpose™* **Probiotic Immune Support™** provides ten valuable strains of friendly flora, selected and balanced to achieve anti-aging and free radical scavenging capabilities.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<b><u>Statement Number</u></b>	<b><u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u></b>
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- |    |   |
|----|---|
| 5. | American Elderberry, Spinach, Parsley, Okra, Oregano, Cumin, Ginger, Arabinogalactan, Milk, Nutritional Yeast, and Bacteria ( <i>L. casei</i> , <i>L. Plantarum</i> , <i>L. salivarius</i> , <i>L. acidophilus</i> , <i>L. rhamnosus</i> , <i>S. thermophilus</i> , <i>B. bifidum</i> , <i>B. infantis</i> , <i>B. longum</i> , <i>B. breve</i> ) |
|----|---|

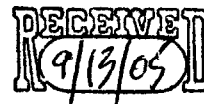
The following identifies the brand name of each supplement for which a statement is made:

<b><u>Statement Number</u></b>	<b><u>Brand Name</u></b>	<b><u>Label or Labeling?</u></b>
5.	Probiotic Immune Support™	Label

I, Kristin Foster, am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: Sept 6, 2005 By: Kristin Foster, QA Administrator  
[Name]  
[Title]

NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93



This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is:

22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is Supercritical Sinus and Respiratory.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Supercritical powder for greater comfort and fast recovery.

(Statement 2): Optimizes wellness through dozens of confirmed immunoactive botanical pathways.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Garlic, Oregano, Echinacea, Elderberry, Goldenseal, Andrographis, Green Tea, Astragalus, Melissa, Myrrh, Wintergreen, Ginger Eucalyptus, Peppermint, Meadowsweet and Purple Willow.
2.	Garlic, Oregano, Echinacea, Elderberry, Goldenseal, Andrographis, Green Tea, Astragalus, Melissa, Myrrh, Wintergreen, Ginger Eucalyptus, Peppermint, Meadowsweet and Purple Willow.

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	Supercritical Sinus and Respiratory	Label and Labeling
2.	Supercritical Sinus and Respiratory	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed August 30, 2005 By: Kristin Foster, Quality Assurance Administrator  
[Name]  
[Title]

05-16062

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is:

22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Supercritical Sinus and Respiratory.**

The text of each structure-function statement for which notification is now being given is:

(Statement 1): From India and Ayurvedic medicine comes *Andrographis paniculata*, which we extract to provide Potency Assured™ levels of andrographolides to modulate immune functioning.

(Statement 2): From China we benefit from astragalus, an adaptogen that promotes immune strength and enhances natural killer cell capabilities.

(Statement 3): From Japan we treasure the immune balancing powder of green tea.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<b><u>Statement Number</u></b>	<b><u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u></b>
--------------------------------	---

- |    |                          |
|----|--------------------------|
| 1. | Andrographis paniculata, |
| 2. | Astragalus               |
| 3. | Green Tea                |

The following identifies the brand name of each supplement for which a statement is made:

<b><u>Statement Number</u></b>	<b><u>Brand Name</u></b>	<b><u>Label or Labeling?</u></b>
1.	Supercritical Sinus and Respiratory	Label and Labeling
2.	Supercritical Sinus and Respiratory	Label and Labeling
3.	Supercritical Sinus and Respiratory	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed August 30, 2005 By: Kristin Foster, QA Administrator  
[Name]  
[Title]

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is:

22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Supercritical Sinus and Respiratory.**

The text of each structure-function statement for which notification is now being given is:

(Statement 1): The world offers comfort during times of challenge from herbs rich with salicin, such as wintergreen, purple willow, and meadowsweet.

(Statement 2): And our dear friend ginger, which we grown on our organic farm in Costa Rica, invigorates us and brings its herbal cousins to life.

(Statement 3): One of nature's most important immune defenders; containing, according to the USDA, at least 36 supportive constituents including the antioxidant compound caracrol.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<b>Statement Number</b>	<b>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</b>
1.	Wintergreen, purple willow and meadowsweet.
2.	Ginger
3.	Oregano

The following identifies the brand name of each supplement for which a statement is made:

<b>Statement Number</b>	<b>Brand Name</b>	<b>Label or Labeling?</b>
1.	Supercritical Sinus and Respiratory	Label and Labeling
2.	Supercritical Sinus and Respiratory	Label and Labeling
3.	Supercritical Sinus and Respiratory	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed

August 30, 2005

By:

Kristin Foster

[Name]

[Title]

Quality Assurance  
Administrator



**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Supercritical Sinus and Respiratory.**

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Fresh supercritical extract delivers the broadest spectrum of nature's most effective immune-supportive organosulphur molecules.

(Statement 2): Combination of Potency Assured™ angustifolia and purpurea extracts synergize to optimally modulate and enhance healthy immune response.

(Statement 3): Israeli research has demonstrated significant potential of this fruit extract's components to support healthy immune function.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<b>Statement Number</b>	<b>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</b>
1.	Garlic
2.	Echinacea
3.	Elderberry

The following identifies the brand name of each supplement for which a statement is made:

<b>Statement Number</b>	<b>Brand Name</b>	<b>Label or Labeling?</b>
1.	Supercritical Sinus and Respiratory	Label and Labeling
2.	Supercritical Sinus and Respiratory	Label and Labeling
3.	Supercritical Sinus and Respiratory	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed

August 20, 2005

By:

Kristin Foster, QA Administrator

[Name]

[Title]

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is:

22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Supercritical Sinus and Respiratory.**

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Long history of use in traditional medicine for its treasured immune-supportive benefits.

(Statement 2): Asian herb extract prized for its ability to modulate immune function with its unique Potency Assured™ compounds called andrographolides.

(Statement 3): A rich source of safe and effective compounds, like polyphenols, valued for countering unfriendly flora and balancing the immune system.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<b>Statement Number</b>	<b>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</b>
1.	Goldenseal
2.	Andrographis
3.	Green tea

The following identifies the brand name of each supplement for which a statement is made:

<b>Statement Number</b>	<b>Brand Name</b>	<b>Label or Labeling?</b>
1.	Supercritical Sinus and Respiratory	Label and Labeling
2.	Supercritical Sinus and Respiratory	Label and Labeling
3.	Supercritical Sinus and Respiratory	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed August 20, 2005

By:

Kristin Foster, QA Administrator

[Name]

[Title]

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Supercritical Sinus and Respiratory.**

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Revered Chinese herb valued in traditional medicine for immune support and in modern research for enhancing natural killer cell activities.

(Statement 2): Natural sources of salicylic acid and other important phytochemicals to promote comfort during the cold and flu season/

(Statement 3): Rich in antioxidant flavonoid compounds to reduce damage caused by free radical stress.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<b><u>Statement Number</u></b>	<b><u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u></b>
1.	Astragalus
2.	Wintergreen, meadowsweet and purple willow
3.	Melissa

The following identifies the brand name of each supplement for which a statement is made:

<b><u>Statement Number</u></b>	<b><u>Brand Name</u></b>	<b><u>Label or Labeling?</u></b>
1.	Supercritical Sinus and Respiratory	Label and Labeling
2.	Supercritical Sinus and Respiratory	Label and Labeling
3.	Supercritical Sinus and Respiratory	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: August 30, 2005

By: Kristin Foster, QA Administrator

[Name]

[Title]

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is:

22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Supercritical Sinus and Respiratory.**

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Long revered for its immune supportive effects to the chest and throat, recent British research shows at least 12 phytochemicals with immune-defensive benefits.

(Statement 2): Time honored remedy to improve respiration and support normal immune functions.

(Statement 3): Time tested remedy for soothing the digestive system and countering unfriendly flora.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<b><u>Statement Number</u></b>	<b><u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u></b>
1.	Ginger
2.	Eucalyptus
3.	Peppermint

The following identifies the brand name of each supplement for which a statement is made:

<b><u>Statement Number</u></b>	<b><u>Brand Name</u></b>	<b><u>Label or Labeling?</u></b>
1.	Supercritical Sinus and Respiratory	Label and Labeling
2.	Supercritical Sinus and Respiratory	Label and Labeling
3.	Supercritical Sinus and Respiratory	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed August 30, 2005

By:

Kristin Foster, QA Administrator

[Name]

[Title]

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is Headache Relief™.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Used for thousands of years for relief from headaches and other painful conditions, recent research shows that ginger possesses numerous constituents that can modulate the formation of inflammatory prostaglandins.

(Statement 2): One of the most sacred therapeutic herbs in Celtic tradition and recommended in ancient Ayurvedic medicine for pain and stomach complaints, meadowsweet is now recognized as a rich source of inflammation modulating salicylic acid.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Ginger
2.	Meadowsweet

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	Headache Relief™	Label and Labeling
2.	Headache Relief™	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed August 26, 2005 By: Kristin Foster, QA Administrator  
[Name]  
[Title]

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR §101.93**

This notification is being filed on behalf of New Chapter, Inc. which is the manufacturer of the product(s) which bear the statements identified in this notification. Its business address is: 22 High St. PO Box 1947, Brattleboro, VT 05302. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is Headache Relief™.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Used traditionally by Native Americans to relieve strained muscles and promote a healthy inflammation response, wintergreen is also recognized as one of nature's richest sources of inflammation modulating salicylic acid.

(Statement 2): Noted by the Greek physician Hippocrates as a valuable herb for pain relief, the herb is now recommended in European pharmacopoeias for its gentle inflammation modulating benefits.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement</u>
1.	Wintergreen
2.	Purple Willow

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1.	Headache Relief™	Label and Labeling
2.	Headache Relief™	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed August 26, 2005

By:

Kristin Foster, QA Administrator

[Name]

[Title]